

ACTyourCHANGE Study Protocol. The Promotion of Healthy Lifestyle for Obese Patients with Acceptance and Commitment Therapy provided with A Modular Approach.

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Study protocol

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Abstract

Background: Acceptance and Commitment Therapy (ACT) resulted to be efficacious in promoting the core process of Psychological Flexibility, a key ability related to physical and psychological health outcomes. Despite evidence-based ACT protocols were applied successfully in different contexts, including the promotion of long-standing behavioral change, the impact of the single processes in the psychological flexibility model remains unclear. The aim of the present study is to evaluate the efficacy of a Focused-ACT intervention for the maintenance of a healthy lifestyle, by separating and evaluating the impact of single core processes targeted into a modular intervention on the maintenance of healthy lifestyle.

Methods: An individually randomized group treatment trial will be conducted. 150 adult obese patients who are attending a four-week medically-based multidisciplinary rehabilitation of weight loss will be randomly allocated into three groups: Module *Engage*, Module *Openness*, and Module *Awareness*. At the beginning (Time 0) and at the end of the intervention (Time 1), at six months (Time2) and one year (Time 3) follow-up weight and height will be recorder and participants will complete the Psychological General Well Being Inventory(PGWBI), the Outcome Questionnaire-45.2 (OQ-45.2), the Brief Values Inventory (BVI), the Committed Action Questionnaire (CAQ), the Italian-Cognitive Fusion Questionnaire (I-CFQ), the Acceptance and Action Questionnaire (AAQ II) and the Five Facet Mindfulness Questionnaire (FFMQ).

Repeated measures 3 (conditions) x 4 (times) will be assessed to examine differences between three groups within four times on both general outcomes measure of weight, BMI, PGWBI and OQ-45.2, and FACT processes targeted during the interventions.

Discussion: By providing additional evidence supporting the relevance of modular transdiagnostic interventions in clinical practice and the use of Process-Based Therapy, this study will contribute to clarify which mechanisms are involved in a generalizable lifestyle behavioral change intervention.

Trial registration

ClinicalTrials.gov Registration number: [NCT04474509](https://clinicaltrials.gov/ct2/show/NCT04474509) Date: July, 4 2020

<https://clinicaltrials.gov/ct2/show/NCT04474509>

Background

Acceptance and Commitment Therapy (ACT; Hayes, Luoma, Bond, Masuda, & Lillis, 2006) is one of the recent third-wave Cognitive Behavioral Therapy (CBT) raised in the last twenty years. It is grounded in Functional Contextualism (Biglan & Hayes, 1996; Hayes & Wilson, 1994) a form of pragmatism based on the principle of “act in the context”, that emphasizes the role of context in understanding the nature and the functions of events that occur. Based on behavioral therapy, ACT is also theoretically rooted in Relational Frame Theory (RFT; Hayes, Gifford, & Ruckstuhl Jr, 1996), a contextual theory of cognition that

conceptualizes human psychological suffering as resulting from the relationship between individuals and their historically and situational-based context.

ACT targets six core processes to promote “psychological flexibility” defined as “contacting the present moment fully as a conscious human being, and basing on what the situation affords, changing or persisting in behavior in the service of chosen values” (Hayes et al., 2006): *Acceptance, Defusion, Contact with the present moment, Self as a context, Values, Committed Actions*. These processes were condensed in the Focused- Acceptance and Commitment Therapy approach (FACT; (Strosahl, K, Robinson, & Gustavsson, 2012) a brief application of ACT-based intervention, which is characterized by three core components:

- *Openness* refers to the willingness to experiencing distress and undesirable private events as part of human experience, without judgment or attempts to avoid or control internal states, even if they are unpleasant. It encompasses the promotion of cognitive defusion, that concerns the relationship between a person and his internal states, including thoughts, feelings, and physical sensations. While a “fused” person acts as thoughts are literally true, instead of perceiving them as mental events (Hayes, Levin, Plumb-Villardaga, Villatte, & Pistorello, 2013), defusion allows distancing from own personal internal states and watch them as objects.
- *Awareness* is the ability to be present at the moment and face events as contextually situated. To be aware means stepping back from suffering situations and seeing them in the context where they occur. This kind of acceptance is a valid alternative to *Experiential avoidance*, that is one of the most important pathological processes that allows people to avoid unpleasant internal events, thoughts, feelings, physical sensations, even though the attempt to escape causes psychological distress.
- *Engagement* in actions linked to personal values, such as relationships, work, spiritual growth. If a person engages himself in committed actions driven by chosen life directions is able to pursue a meaningful and coherent life.

FACT resulted in a promising evidence-based behavioral intervention, particularly suitable to health care settings, due to his brief nature and his adaptation in group settings (Glover et al., 2016).

Glover and colleagues, (2016) provided findings in support of the efficacy of a brief – 4 group sessions FACT protocol in producing improvement of perceived quality of life and reducing stress, anxiety, and depressive symptoms in 51 patients in a primary care setting.

Since Psychological Flexibility model is complex, it could be interesting to study the specific role of every single sub-component abovementioned, in order to deepen the effect of Psychological Flexibility on health and well-being (Levin, Herbert, & Forman, 2017; Levin, Krafft, & Twohig, 2020).

To do so, one possible approach is the modularization of treatment provided to foster Psychological Flexibility into specific modules each of whom related to every single sub-component.

Modularization has been described as an attempt to break complex activities in single components that act independently. A single module is a unit within a whole intervention that is expected to produce an intended result in therapy, while interacting with each other component of the structure, but maintaining his function limited to the module, without interfering with others.

Unpacking the manualized intervention into specific modules allows therapists to personalize intervention for the need of individuals, while preserving the standardization of therapy, according to evidence-based guidelines (Chorpita et al., 2013; Villatte et al.,2016).

With this work, we propose a treatment protocol based on the application of a FACT- oriented group psychological treatment, applied in a single health care center for obesity management. The main scope of the intervention is to promote some crucial psychological abilities for stable behavioral change, to foster the long-term adoption of a healthy lifestyle, in obese patients undergoing treatment for weight management, according to the FACT model.

The aim of the present study is twofold: The first aim is to evaluate whether our intervention is effective in producing noticeable changes in processes targeted within the modules. The second clinically-relevant interest is to test the specific impact of each single core process of FACT on the ability to change behaviors permanently, in order to maintain a healthy lifestyle.

Due to the novelty of our intention, it is difficult to perform well-defined hypotheses. The only expectation is to find the pre-to-post intervention improvement in psychological processes, given by the effect of each module provided, and a general change in treatment outcomes.

Methods

Study design

A three-arm Individually Randomized Group Treatment Trial (IRGT) will be conducted (Andridge, Shoben, Muller, & Murray, 2014; Pals et al., 2008). Participant enrolled for the study will be randomly allocated into three experimental conditions attended during the inpatient phase:

1. Module *Engage*
2. Module *Openness*
3. Module *Awareness*.

At the beginning (Time 0), at the end of intervention (Time 1), after 6 months (Time 2) and 12 months (Time 3) follow-up, weight, height and the battery of questionnaires addressing outcome and process measures will be collected.

Also, at discharge, they will receive wearable devices for the daily recording of habits regarding diet and physical activity. They are asked to wear devices for one month just after discharge in order to test the ability to follow over time the medical recommendations and maintain long-standing healthy habits.

During this period, all the participants are monitored, with the support of technology, using wearable devices and mobile app to measure their healthy habits.

Participants

Participants will be obese patients enrolled for a weight loss rehabilitation program in a single clinical center in the North of Italy. Patients will be included if they will meet these following inclusion criteria: 1) age between 18 and 65 years; 2) BMI>30; 3) clinical recommendation for the group psychological treatment (basing on the internal procedures of the structure described in the Procedures section) 4) written and informed consent to participate; 5) being technology friendly to use wearable devices.

Exclusion criteria for the study are: 1) other psychiatric disturbances (diagnosed according to DSM 5 criteria); 2) other medical conditions not related to obesity that could compromise participation at the study.

Measure

Outcome measures

The primary outcome of the study is weight loss maintenance. *Weight*, and *height* will be assessed to calculate Body Mass Index (BMI= kg/m²). Success in weight loss is achieved if individuals lose at least 5% of initial weight at the end of treatment and maintains the percentage of weight lost for at least one year (Wing & Hill, 2001).

The second outcome measure is psychological well-being. The *Psychological General Well-Being Inventory* (PGWBI; (Dupuy, 1984) Italian validation of Grossi and colleagues (Grossi et al., 2006) consists of 22 self-administered items rated on a 6-point Likert scale, relative to six subscales that offer a measure of the level of subjective psychological well-being. Subscales are anxiety, depression, positive well-being, self-control, general health, and vitality with a range of Alpha's scores from 0.61 to 0.85 for each subscale.

The third outcome measure is the outcome of psychological treatment. The *Outcome Questionnaire-45.2* (Lambert, Gregersen, & Burlingame, 2004) Italian version by Chiappelli, Coco, Gullo, Bensi, e Prestano (2008) as a measure for the assessment of psychological treatment. It is a self-report questionnaire composed of 45 items. Subscales are symptoms distress, interpersonal relations, and social role functioning. The total Alpha score is excellent (.90 for clinical sample; .92 for non-clinical sample).

ACT Processes measures

Module Engagement

The *Brief Values Inventory* (McCracken & Yang, 2006) Italian validation of Baroni, McCracken, Matera, Nerini, & Stefanile (2019). It is composed by 12 items aimed to assess the success in living according to

personal values. The internal consistency of the Success subscale is .70 in the Italian validation study.

The *Committed Action Questionnaire* (McCracken, 2013) Italian adaptation of Baroni, Matera, Nerini, & Stefanile (2017) is 8-items self-report questionnaire rated on 7-point Likert scale, used to assess positive and negative aspects of the ability to engage themselves into committed actions driven by values. The internal consistency of the measure tested on a normative sample was good ($\alpha = .80$).

Module *Openness*

The *Italian-Cognitive Fusion Questionnaire* (Gillanders et al., 2014) Italian version by Oppo and colleagues (2019) is 7-items questionnaire administered for the assessment of cognitive fusion. The internal consistency of the Italian version is excellent ($\alpha = .82$).

The subscale “*Nonjudge*” of the *Five Facet Mindfulness Questionnaire*, described below, is used as a measure of Acceptance. The internal consistency of the subscale is .86

Module *Awareness*

The Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). The Italian version (Boffito et al., 2009) is 39-item-self-report questionnaire used as a measure of Mindfulness. It is composed by five subscales: observe, describe, act with awareness, non-react, nonjudge. The internal consistency of total scale is good ($\alpha = .86$).

Psychological flexibility

The Acceptance and Action Questionnaire (AAQ II; Bond et al., 2011). The Italian version (Pennato, Berrocal, Bernini, & Rivas, 2013) is the most widely used self-reported questionnaire that measures psychological inflexibility and experiential avoidance. It is composed by 10 items, rated on 7-point Likert scale, the Internal consistency is good ($\alpha = .83$) and test-retest reliability is moderate (.61)

Monitoring measure

Another measure concerns healthy lifestyle monitoring relative to the period of one month after discharge: Indicators are: 1) total amount of moderate-to-vigorous physical activity in minutes; 2) weekly mean of daily total amount of calories; 3) weekly mean of total daily steps.

All data collected will be stored in cloud computing and provided to researchers through a dedicated web platform.

Procedures

At the beginning of the study (Time 0), weight and height of participants will be assessed to calculate Body Mass Index (BMI: Kg/m²) and PGWBI, OQ-45.2 BVI, CAQ, I-CFQ, AAQ II and FFMQ will be administered.

Accordingly to recent guidelines for the management of adult obesity (Giusti et al., 2020; Yumuk et al., 2015), all patients will attend the rehabilitation program composed by medical, nutritional physical and psychological components. Patients will follow a hypocaloric balanced diet provided by dietitians (energy intake around 80% of the basal energy expenditure estimated, according to the Harris-Benedict equation). They will take part in a nutritional counseling program provided both in individual and group sessions focused on nutritional education, information on obesity and their health-related risks, setting personal goals for weight loss, weight management, behavioral changes, and prevention of relapses.

The patients will perform physical activity once a day (one hour) with trainers and physiotherapists consisting of programs of aerobic activity, postural gymnastics, and walking. They also will receive psychological assessment provided by clinical psychologists expert in health psychology, aimed to assess the individual characteristics including physical and psychological well-being of the patients, the possible presence of Eating Disorders on any other psychological disturbances including mood dysregulation, anxiety, depression, investigate the presence of familial and social support, the level of motivation of change and the willingness to engage themselves into a stable lifestyle habits change. Basing on their needs, patients will receive psychological support provided both in individual and in group settings.

Patients enrolled for the study will follow followed the medical, nutritional and physical rehabilitation program, while with respect to the psychological component, they will be randomly allocated into three experimental conditions:

1. Module *Engage*
2. Module *Openness*
3. Module *Awareness*.

A detailed description of the condition will be provided as follow.

The randomization will be performed using the proper web site (www.randomization.com).

All conditions comprise 2 group sessions, provided twice a week, lasting about one hour each. Sessions will be delivered by an expert clinical psychologist in ACT and will include experiential exercises and metaphors. A detailed description of the sessions will be included in the following section.

At the end of the treatment (Time 1), after 6 (Time 2) and 12 months (Time 3) the outcome and process measures (PGWBI, weight, BMI, OQ-45.2, BVI, CAQ I-CFQ, AAQ-II and FFMQ) will be repeated. During the inpatient phase the measures will be directly administered, while at 2 points follow-up data will be collected via online survey.

Participants also received wearable devices and will be instructed on how to use wearable for the following one month, after discharge.

Adverse events or other unintended effects of trial intervention could be managed by the researchers involved in the study.

Those who suffer from trial participation can consult the psychologist responsible for the hospital division.

Completed informed and written consent will be delivered to the responsible of the study.

All personal information about participant and records of all patients will be collected and preserved separately, in a secure place, into password-protected files kept for five years after the end of trial

The Medical Ethic Committee of Istituto Auxologico Italiano approved the study.

Intervention

ACT Module on *Engagement*

During this module, patients will have the opportunity to increase their motivation to change and encourage the engagement in committed actions, consistent with their life values. Patients are invited to reflect on what is important in their lives, which values make their life worth living, and which actions they could take to live a meaningful life, in accordance with personal values. The use of metaphors and experiential exercises will facilitate the process of exploring personal values, identifying life directions and related behaviors. For example, the 80th Birthday Party metaphor requires participants to imagine there is a party in honor of their birthday and the time comes when people are starting to give speeches and try to answer the question about what they want to hear people at the party say. This exercise help patients in wondering what person they want to be with themselves and others.

ACT Module on *Openness*

Participants attending this module are guided to recognize and distancing themselves from stressful thoughts, feelings and sensations. They will learn to read suffering as part of human experience, without self-judgment and self-condemnation. Rather, the psychologist will encourage the patient's assumption of an open and acceptable approach to internal experiences. Throughout the module, the psychologist will help patients to reflect on their usual, but ineffective efforts to solve personal problems, and encourage the adoption of new responsive strategies based on acceptance and defusion from personal distress.

An example of a metaphor used during the Module is The Passenger on a bus. In this metaphor, patient have to imagine to be a driver bus and his every thought is a passenger that gets on and off the bus. This exercise help patients to accept, defuse from, and reduce the power of their thoughts.

ACT Module on *Awareness*

The module comprises meditation exercises and experiences aimed to learn how to act intentionally with awareness about personal thought and sensations without automatically reacting. Participants are

supported to recognize their actions and the context where they occur and learn to choose to respond with action consistent with their values and not automatically. The psychologist

will propose breathing exercises, body scan and others mindfulness experiences. Participants will be encouraged to sitting comfortably, close the eyes, feel themselves in contact with the present moment they are living, paying attention to their breath, noticing the rhythm and any other aspect of the experience of breathing. Then, the therapist guides the participant's attention on the body, noting any part of their body from the head to feet. Then, the sounds around, any noises that could distract their attention on themselves.

Treatment fidelity

The research group comprises licensed psychologists, researchers, and doctoral student experts in the field of clinical interventions in health care settings and research. Group sessions will be administered by a clinical psychologist with many years of expertise in ACT clinical practice both in individual and group settings, blinded to research scopes. The structure and the content of modules are consistent with ACT theory. Two bachelors-level observers, also blinded to research, after a period of training, will attend at least 20 % of sessions to evaluate the adherence to the protocol, the coverage of contents and the use of any additional strategies. They will use a checklist detailed for all the content of each module, including the process targeted, experiential exercises and metaphors planned for each session. Coders have to achieve a minimum of 80% reliability with the expert trainers and each other. With lower level of agreement, the data will be dismissed. (Villatte et al., 2016).

Statistical analysis

Sample size has been calculated for a 3 (between) x 4 (within) ANOVA using G*Power software (release 3.1.3) (Faul, Erdfelder, Lang, & Buchner, 2007). Setting alpha to 0.05, power to 0.80, the correlation among repeated measures to 0.5 and the non-sphericity correction to 1, a total sample of 45 participants are required to detect a small-size interaction effect ($f = 0.20$).

Taking into account a possible correlation among observation within groups measured in a previous study (Interclass Correlation Coefficient: ICC= 0.15; Cattivelli et al., 2020), a number of participant per groups of 7, the variance inflation factor (Donner, Birkett, & Buck, 1981) was 1.9

With a possible dropout of 10% at follow-up, the final number of participants needed for the study is 90.

$[(45 \times 1.9) + 10\%]$

Data will be analyzed on an Intention-To-Treat basis using a 3 (conditions) x 4 (times) repeated measure Analysis of Variance (ANOVA) to examine differences between three groups within four times on both general outcomes measure of weight, BMI, PGWBI and OQ-45.2, and ACT processes targeted during the interventions (BVI, CAQ, I-CFQ, and FFMQ) including the general measure of Psychological Flexibility

(AAQ II). Corrected effect sizes (Hedges's g) and significance at 95% confidence interval (CI 95%) will be calculated for both between-group and within group differences.

Analysis will be performed using IBM Statistical Package for the Social Sciences (SPSS) version 26.

Discussion

The current study aims to provide additional evidence supporting the relevance of promoting Psychological Flexibility in order to foster healthy lifestyle and improve general subjective well-being through a modular transdiagnostic intervention suitable for clinical practice.

Modularization makes the intervention more practical, integrative, flexible, and patient-centered. Also, the modular treatment allows clinicians to suit the intervention with their expertise and the need of patients (Rotheram-Borus, 2012) by orienting therapist in selecting the modules (Chorpita, Daleiden, & Weisz, 2005).

Modularized treatment is also coherent with the raising interest for the Process-based research focused on understanding the processes involved in human suffering rather than addressing symptoms reduction.

The present study is quite innovative for different reasons. Firstly, to the author's knowledge, this is one of the first attempts to evaluate the impact of single targeted processes of FACT on affecting healthy lifestyle change. Focusing on the mechanism of change could clarify which factors are involved in a generalizable lifestyle behavioral change intervention.

Another relevant strength is determined by the experimental design of the study. The IRGT for the evaluation of the effectiveness of interventions is characterized by the randomization of individuals into experimental conditions in which treatment is delivered in groups. These designs are very common in the field of public health because they are practice and less expensive and take into account the influence of the group environment where the intervention is provided (Pals et al., 2008).

It is important to notice also the advantages of using wearable devices in the outpatient phase, as a direct measure of healthy habits followed by patients in their daily life context.

Nonetheless, several limitations must be pointed out. This study will not include the control group or comparison with another intervention.

In addition, IRGT requires proper analytic methods that should take into account the influence of a potential correlation among observations within treatment conditions (Pals et al., 2008).

Due to the relatively small number of sessions and previous evidence suggesting the non-significance effect of the treatment groups (Cattivelli et al., 2020) found in a similar previous study, we assume to adopt a traditional statistical analysis method, even if the assumption of the independence of the

observation is violated. To deal with this limitation, the variance inflation factor was taken under consideration in sample size calculation.

Another limitation is represented by the highly specific context where the study will take place, limiting the external validity of the research.

Despite these limitations, the study could represent an important advancement in the field of the theoretical development of the Psychological Flexibility model, with also relevance for the clinical practice.

Abbreviations

CBT	Cognitive Behavioral Therapy
ACT	Acceptance and Commitment Therapy
FACT	Focused- Acceptance and Commitment Therapy
IRGT	Individually Randomized Group Treatment Trial
BMI	Body Mass Index
PGWBI	Psychological General Well Being Inventory
OQ-45.2	Outcome Questionnaire-45.2
BVI	Brief Values Inventory
CAQ	Committed Action Questionnaire
I-CFQ	Italian Cognitive Fusion Questionnaire
AAQ-II	Acceptance and Action Questionnaire
ICC	Interclass correlation coefficient
ANOVA	Analysis of variance

Declarations

Trial status

Protocol version: Protocol Version 1.0 Date: 22/07/2020

Data collecting began in September 2020 and will be completed in Mach 2021.

Ethics approval and consent to participate

The Medical Ethic Committee of Istituto Auxologico Italiano approved the study.

The study personnel and the Ethical Committee will ensure that the study is conducted within appropriate professional ethical guidelines, ensuring that Good Clinical Practice guidelines are observed. All participants provide written informed consent before participating in the trial or extension study.

Competing interests

The authors declare that they have no competing interests

Funding

The trial will be self-funded by the investigators.

Consent for publication

Not applicable

Availability of data and material

The datasets generated and/or analysed during the current study will be available from the corresponding author on request. Records of all patients will be kept separately in a secure place. We plan to communicate trial results to participant with a final report provided via e-mail. Result will be available for the scientific communication and health care experts via publication on scientific journal and participation into national and international congresses.

Authors' contributions

AGU and RC conceived the study, planned the experimental design and made substantial contribution to the manuscript drafting. SC, IB, GV, VV, AC, VG, MB; CV, GC, AM, participated in the implementation of the study, including the allocation, enrollment and assignment of patients to interventions, and contributed greatly to the manuscript drafting. GP FVR, GMM, GC, EM participated in the study design and helped to draft the manuscript. EG defined the statistical analysis we are planning to use for the data collected and establish the sample size for the study. All authors read and approved the final manuscript.

Confidentiality

Completed informed and written consent will be delivered to the responsible of the study.

All personal informations about participant and records of all patients will be collected and preserved separately, in a secure place, into password-protected files kept for five years after the end of trial.

Communication

We plan to communicate trial results to participant with a final report provided via e-mail. Result will be available for the scientific communication and health care experts via publication on scientific journal and participation into national and international congresses.

Acknowledgments

Not applicable

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